

## REMARKS

In the Office Action dated November 21, 2002, claims 69-71 and 73-90 are pending.

Claims 69-71 and 76-77 are under consideration. Claims 73-75 and 78-90 are withdrawn from consideration. Claims 69-71 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Roberts et al. (U.S. Patent 5,616,328). Claims 76-77 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Roberts et al.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 69-71 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Roberts et al. (U.S. Patent 5,616,328).

It is observed that claim 69 is directed to a vaccine composition against *Actinobacillus pleuropneumoniae* that comprises five polypeptides, which initially were isolated from strain WF-83, together with an adjuvant and a carrier. The vaccine is for immunization of pigs. Claims 70 and 71, which depend from claim 69, are directed to certain preferred vaccine compositions. Specifically, in claim 70, one or more of the polypeptides in the vaccine compositions is fused to a carrier; and in claim 71, the vaccine composition further comprises an additional immunomodulatory component.

The Examiner contends that Roberts et al. disclose a vaccine composition against *Actinobacillus pleuropneumoniae* that comprises at least 5 proteins/polypeptides from strain WF-83 (col. 8, lines 1-40), together with an adjuvant (col. 8, line 18) and a carrier (col. 8, line 21). The Examiner also contends that Roberts et al. disclose at col. 8, lines 4-14, a vaccine composition where the proteins/polypeptides in the vaccine are fused to a carrier through the addition of

glutaraldehyde and lysine, and where the vaccine further comprises the Amphigen adjuvant (col. 8, line 34) or carbohydrate (col. 8, line 30 and col. 6, lines 17-21) as the additional immunomodulatory component.

Applicants respectfully submit that independent claims 69 and 76 have been amended to add the recitation “substantially purified” in front of the term “polypeptide” wherever this term appears. That is, the five polypeptides present in the vaccine composition are each in a “substantially purified” form. Support for this amendment is found throughout the specification, e.g., page 4, ln. 4, page 8, ln. 20-21, ln. 30-31, page 9, ln. 4-5, ln. 14-15 and ln. 24-25. As defined in the specification at page 29, lines 16-17, a protein is “substantially purified” where the protein constitutes more than about 20 wt% of the protein in a particular preparation. The five polypeptides present in the claimed vaccine composition can be obtained and purified from the membrane protein fraction prepared from *A. pleuropneumoniae*, as illustrated at pages 40-41 of the specification. Alternatively, the five polypeptides can be recombinantly expressed in bacterial host cells and purified from these host cells, as illustrated at pages 52-54 of the specification.

Applicants further submit that Roberts et al. merely teach a vaccine composition prepared using an extract of cells of *Actinobacillus pleuropneumoniae*. The extract was prepared by heating a suspension of cells of *Actinobacillus pleuropneumoniae* with agitation for one hour, centrifuging the heated suspension and collecting the supernatant. There is no indication that such extract prepared by Roberts contains the five polypeptides of the claimed vaccine composition, let alone the five polypeptides in a “substantially purified” form. There is absolutely no teaching or suggestion in Roberts et al. to purify the five polypeptides which are employed in the presently claimed vaccine composition. Therefore, Roberts et al. do not teach or suggest the claimed vaccine composition.

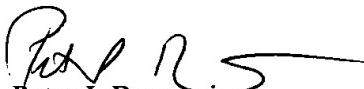
Accordingly, the rejection of claims 69-71 as allegedly anticipated by Roberts et al. is overcome. Withdrawal of the rejection is respectfully requested.

Claims 76-77 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Roberts et al. The Examiner concedes that the vaccine composition disclosed by Roberts et al. differs from the instantly claimed invention by failing to show the vaccine composition in kit form. The Examiner contends that it would have been obvious to the person of ordinary skill in the art at the time the invention was made to formulate the vaccines in a kit for the purpose of commercial distribution, and for the convenience of the end user who will administer the vaccine to the animals.

Applicants reassert that Roberts et al. do not teach or suggest a vaccine composition that comprises the five polypeptides in a substantially purified form, as employed in the presently claimed vaccine composition. Therefore, Roberts et al. do not render the presently claimed vaccine composition obvious, regardless of whether the vaccine composition is in a kit form. Accordingly, the rejection of claims 76-77 as allegedly rendered obvious by Roberts et al. is overcome. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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